



## FDA's Sentinel of Public Health: Field Staff Safeguards High Standards

As an agency that protects the health of all Americans, the FDA must keep in touch with consumers and firms dealing with regulated products all over the United States. Regulating **115,000 business establishments** that annually produce, warehouse, import and transport \$1 trillion worth of consumer goods is no small task. The FDA devotes to this crucial task, which is directed by the **Office of Regulatory Affairs (ORA)**, about one-third of the agency's personnel. Stationed in more than 150 offices, resident posts and laboratories from coast to coast and in Puerto Rico, ORA's highly trained staff provides the eyes, ears and the long arm of the agency that ensures the implementation of the FDA's high public health standards.

Here are some of the major activities of ORA specialists:

- **Consumer safety officers (CSOs)** and inspectors conduct about 16,000 domestic and foreign inspections a year to ensure that regulated products destined for the U.S. market meet the agency's standards. Plants are inspected both before the FDA approves a product, to make sure that the firm has the capacity for high-quality production, and periodically afterwards, to ascertain that it follows appropriate manufacturing processes. ORA's CSOs also monitor clinical trials that precede the products' submissions for the FDA's approval.
- **Scientists** in ORA's 13 laboratories analyze about 30,000 products each year to determine their adherence to the FDA's standards. The analyzed products include samples

### ORA's Increased Strength

The FDA's ability to protect the public health has been enhanced by additional resources authorized by Congress in the wake of the September 11, 2001, terrorist attacks. The FDA is in the process of hiring 655 new ORA employees, 600 of whom will strengthen the food safety, 35 will enhance the safety of animal drugs and feed, and 20 will be part of the drug, biologic and device programs. When the hiring is complete, by the end of 2002, ORA anticipates that about 420 of the new inspectors and other employees either will be stationed at border locations, or will be working specifically on imports. All of the new hires will be trained in both import and domestic operations to help ensure adequate coverage of both domestically manufactured and imported products.

### ORA's Regional and District Offices



of the 7 million import shipments that are overseen by ORA inspectors in the nation's ports of entry. Imported products that do not measure up to FDA standards are not

allowed on the U.S. market.

- **Public affairs specialists** reach out to consumer groups, health-care professionals, and state health authorities to explain FDA policies and encourage compliance with FDA standards. In addition to briefing interested groups and responding to press inquiries, these specialists work together with the rest of the field staff to rapidly respond to public health emergencies caused by natural disasters and product problems.

**For more information**, please call ORA at 301-827-3101 or visit the FDA Web site at [www.fda.gov/ora](http://www.fda.gov/ora).

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